UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,049	10/02/2001	Chih-Ming Chen	300.1033US	8670

23280 7590 03/09/2004

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 SEVENTH AVENUE, 14TH FLOOR
NEW YORK, NY 10018

EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1615	15

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/970,049	CHEN, CHIH-MING	
	Examiner	Art Unit	
	Simon J. Oh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,6,16,17,19,20 and 22-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6,16,17,19,20 and 22-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's petition for amendment, response, petition for extension of time, request for continued examination, and information disclosure statement, all received on 17 February 2004.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over Eek in view of Depui *et al.* is withdrawn.

The rejection of Claim 21 under 35 U.S.C. 103(a) as being unpatentable over Källgren in view of Depui *et al.* is withdrawn.

Claims 3, 6, 16, 17, 19, 20, 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Källgren, Depui *et al.*, and Eek.

The Källgren patent teaches blister pack comprising at least a first and second row of blisters, perforated in such a way that individual blisters may be individually separated from the pack (See Abstract; Column 2, Lines 38-52; and Figures). The disclosed blister pack may be used for drugs such as omeprazole. Additionally, the blister pack is useful for packaging drugs that should be administered in combination (See Column 3, Lines 4-41).

The Källgren patent does not explicitly teach the use of the disclosed pack with a combination of a proton pump inhibitor and a non-steroidal anti-inflammatory drug.

The Depui *et al.* patent teaches a drug combination comprising a proton pump inhibitor and a non-steroidal anti-inflammatory drug (See Abstract). Omeprazole and lansoprazole are listed as suitable proton pump inhibitors; naproxen is listed as a suitable non-steroidal anti-inflammatory drug (See Column 6, Line 1 to Column 8, Line 13). A tablet comprising lansoprazole and naproxen is disclosed (See Example 4). The use of these drugs in separate dosage forms in a combination therapy in the prior art is acknowledged in the disclosure (See Column 2, Lines 32-40). Suitable dosage ranges for each category are listed; each dosage form will preferably comprise 10 to 80 mg of the proton pump inhibitor and 10 to 800 mg of the non-steroidal anti-inflammatory drug (See Column 14, Lines 7-25)

The Eek document discloses drug packaging consisting of blister pack cards that may be assembled to form a combination pack of dosage forms, such as tablets (See Abstract; Page 1, Lines 5-12; and Figures). The scope of the disclosed invention encompasses dosage units of different drugs or different amounts of drugs within a single blister pack (See Page 5, Lines 8-14). Digital notation may be printed on the pack for the benefit of the patient. Alternatively, other notation may be printed, such as the time of day or the day of the week for the dose to be taken (See Page 7, Lines 7-11). Methods of treating disease using a combination blister pack are also disclosed (See Page 5, Lines 1-6).

It would be obvious to one of ordinary skill in the art at the time the instantly claimed invention was made to combine the disclosures of Källgren, Depui *et al.*, and Eek into the objects of the instantly claimed invention. It is the position of the examiner that one of ordinary

skill would be motivated to combine the disclosures of Källgren, Depui *et al.*, and Eek in order to create a packaging system comprising a proton pump inhibitor in combination with a non-steroidal anti-inflammatory drug. As stated in Depui *et al.*, the administration of a non-steroidal anti-inflammatory drug in combination with a proton-pump inhibitor is known and that patient compliance is a main factor in devising a successful treatment. It is the position of the examiner that similarly, a combination dosage regimen given in a packaging system designed for that purpose, as disclosed in Källgren and Eek, will also lead to greater patient compliance. It is the position of the examiner that one of ordinary skill in the art that would recognize that the aims of the Källgren, Depui *et al.*, and Eek are similar in the area of improving patient compliance. As the disclosed invention of Källgren is not limited to any particular types of drugs to be packaged, one of ordinary skill can expect to create a drug pack comprising dosages of lansoprazole and naproxen in accordance with a combination dosage regimen with a reasonable expectation of success.

Thus, the instantly disclosed invention is prima facie obvious

Response to Arguments

Applicant's arguments filed 17 February 2004 have been fully considered but they are not persuasive.

As stated above, the motivation to combine the prior art references comes their common goal of improving patient compliance. The prior art has already disclosed using the same drugs in a combination therapy in ranges of dosage amounts, which encompass the dosage amounts claimed in the instant application. That the Depui *et al.* patent discloses an alternate method of

improving patient compliance in this combination therapy does not bar it, in the view of the examiner, from being properly applied as prior art against the instant claims, and as such, the claims are an obvious extension of the disclosure of the prior art.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1615

sjo

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600